REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Claims 1, 13, 14, and 31 are pending in this application. Claims 15, and 17-30 have been withdrawn from consideration. By the foregoing amendment, claim 1 has been amended to recite " a concentration of the nitroimidazole derivative is 1.5 to 5 % by weight based on the amount of the preparation" Support for this amendment can be found on page 41, line 16 of the Specification as originally filed. Claim 31 has been canceled without prejudice or disclaimer to the subject matter recited therein.

Response to Rejections Under 35 U.S.C. §103

Claims 1, 13, 14 and 31 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goodman et al. (PCT International Publication No. WO/27960) in view of Fleischer (1999, Abstract Only) or Fleischer (1999); and Miller et al. (1980 Abstract Only). The rejection is respectfully traversed.

The Examiner has asserted that Goodman et al. teach a viscous hydrogel composition containing nitroimidazole (e.g. tinidazole) for treating inflamed skin diseases such as rosacea and eczema, and Example 1 uses about 0.75wt% of tinidazole. The examiner has contended that it would be obvious to treat atopic dermatitis using the treatment of Goodman et al., because the cited secondary references allegedly teach that dermatitis is a form of excema and that immune regulation may be implicated in atopic dermatitis. OFFICE ACTION DATED MAY 14, 2008, at 3.

A treatment comprising 0.75 wt % of tinidazole may be effective for the treatment of rosacea according to the examples of Goodman et al.. However, the treatment taught by Goodman et al. is not effective for the treatment of atopic dermatitis and is not suggested for treatment of atopic dermatitis by Goodman et al. or any other prior art. Thus, Goodman et al. does not demonstrate a treatment of atopic dermatitis or a treatment that could be effectively modified for as a treatment of atopic dermatitis as the Examiner has contended. A person of ordinary skill trying to apply the example of Goodman et al. to treat atopic dermatitis would not obtain satisfactory results. By contrast, the present inventors have shown for the first time that higher concentrations of nitroimidazole, concentrations not contemplated by Goodman et al., are effective as recited in the present claims.

Treatment of atopic dermatitis is not an approved indication for 0.75 wt% of metronizadole. Galderma Laboratories obtained FDA approval for "MetroLotion" for dermatology (see attached Exhibit A). Although Exhibit A does not expressly indicate the concentration of metronizadole, MetroLotion is an external preparation containing- 0.75 wt% of metronizadole, which concentration is the same as that in "MetroCream" and "MetroGel." Exhibit A discloses "MetroLotion" for as a dermatology treatment only for treatment of rosacea and also discloses that MetroLotion Topical lotion is contraindicated in individuals with a history of hypersensitivity to metronidazole. Galderma Laboratories obtained further FDA approvals on "MetroCream" and "MetroGel" which are extern al. preparation containing 0.75 wt% of metronizadole (see Exhibits B and C, attached hereto). Exhibits B and C indicate only the treatment of inflammatory papules and pustules of rosacea. See also, Physician's Desk Reference (1996), at 1047 (Exhibit D).

Exhibits A-D, which disclose the approved uses of 0.75 wt% metronizadole, do not indicate that the external preparations are effective in the treatment of atopic dermatitis.

Indeed, external preparations containing 0.75 wt% of metronizadole are not satisfactory for the treatment of atopic dermatitis.

Curatek Pharmaceuticals, Inc. filed PCT application W0 89/06537 (previously of record) that discloses uses of compositions such as MetroLotion, MetroCream and MetroCel. W0 89/06537 does not suggest the high concentrations of 1.5 to 5% recited in the present claims. Indeed, Curatek Pharmaceuticals teaches against the concentrations used in the presently claimed treatment. Curatek Pharmaceuticals teaches that the highest concentration of metronizadole is 1 wt%. W0 89/06537, at 8, line 6 and claim 3. Furthermore, for the reasons that metronidazole is contraindicated in individuals with a history of hypersensitivity, those skilled in the art would not have been motivated to try metronizadole in concentrations as high as 1.5 to 5% by weight based on the amount of the preparation as recited in the resent claims. In addition, although this PCT application is directed to a dermatological preparation for topical application (see claim 1), it specifically discloses topical treatment of rosacea (see page 13, line 18 and page 15, lines 27 to 30) but is silent with the treatment of atopic dermatitis. Thus, despite disclosing the use of metronizadole for dermatology, Curatek Pharmaceuticals failed to consider that metronizadole at the presently recited concentrations could be applied to the more difficult problem of treating atopic dermatitis. This provides further evidence that persons of ordinary skill in the art would not consider treatment of atopic dermatitis as an obvious application of treatments of other forms of dermatitis such as rosacea.

Goodman presented no working examples wherein atopic dermatitis is treated, nor suggests use of metronizadole in high concentration such as 1.5 to 5wt%. The cited secondary references do not cure the deficiencies of Goodman et al., because the combination of those references would not have overcome the knowledge in the art that different forms

dermatitis require different treatments and that atopic dermatitis is particularly difficult to treat. Neither of Fleischer and Miller suggests that a preparation containing 1.5 to 5% by weight of the nitroimidazole derivative can treat atopic dermatitis. Applicants have previously presented evidence that atopic dermatitis is clearly distinguished from rosacea and eczema, and is recognized as most difficult form of dermatitis to be treated.

By contrast to the teachings of Goodman et al., the Test Examples 1 to 8 in the present specification present results that are not suggested anywhere in the prior art obtained using preparations containing 1.8 to 3 wt % of nitroimidazole derivative in the treatment of atopic dermatitis as shown below, obtaining excellent effects.

Test Example 1:	2 wt% of metronizadole (preparation of Example 1)
Test Example 2:	1.8 wt% of metnmizadole (preparation of Example 4)
Test Example 3:	2 wt% of tinidazole (preparation of Example 11)
Test Example 4:	1.8 wt% of tinidazole (preparation of Example 11)
Test Example 5:	2 wt% of metroniza.dole (preparation of Example 21)
Test Example 6:	2 wt% of metronizadole (preparation of Example 22)
	2 wt% of Ill etronizadole (preparation of Example 51)
Test Example 7:	2 wt% of tinidazole (preparation of Example 23)
	3 wt% of tinidazole (preparation of Example 25)
Test Example 8:	2 wt.% of tinidazole (preparation of Example 11)
	2 wt% of tinidazole (preparation of Example 24).

As shown by Test Examples 1 to 8, the present inventors have succeeded where others have failed. The present inventors demonstrated for the first time the treatment of atopic dermatitis by use of a preparation containing 1.5 to 5% by weight of nitroimidazole derivative.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: September 15, 2008

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